



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG - 4 2004

Mr. Ira W. Berman
Chairman of the Board of Directors
CCA Industries, Inc.
200 Murray Hill Parkway
East Rutherford, New Jersey 07073

Dear Mr. Berman:

This is in response to your letter to the Food and Drug Administration (FDA) dated May 28, 2004. Your letter was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that CCA Industries, Inc. is marketing a product named Mega-T Chewing Gum as a dietary supplement.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). Your product is expressly identity labeled as "chewing gum." The term "food" is defined in 21 U.S.C. 321(f) and means, among other things, "[C]hewing gum." 21 U.S.C. 321(f)(2). Therefore, chewing gum is a conventional food. Since you have identity labeled your product as a conventional food, it is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional and you have any questions about the status of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

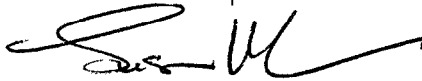
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Page 2 - Mr. Ira W. Berman

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Susan J. Walker', with a stylized flourish at the end.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

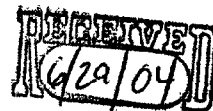
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-CE340



Ira W. Berman
Chairman of the Board
cca5@earthlink.net

Certified Mail/Return Receipt Requested



May 28, 2004

Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS 800)
Food and Drug Administration
200 C Street CW
Washington, DC 20204

Re: CCA Industries, Inc.
Mega-T Chewing Gum

Dear Sir or Madam:

Enclosed in triplicate is the fully executed **NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT** for the above referenced product as required by the FDA.

Very truly yours,

A handwritten signature in dark ink that reads "Ira W. Berman". The signature is fluid and cursive, with a stylized "I" and "B".

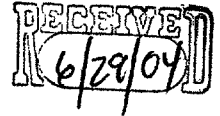
Ira W. Berman
Chairman of the Board of Directors

/s

88797

May 28, 2004

Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS 800)
Food and Drug Administration
200 C Street CW
Washington, DC 20204



**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

This notification is filed by CCA Industries, Inc.

200 Murray Hill Parkway, East Rutherford NJ 07073

to section 403 (r)(6) of the Federal Drug and Cosmetic Act, 21 USC §343 (r)(6).

Name of Dietary Supplement:	Mega-T Chewing Gum
Name of Dietary Ingredient:	green tea leaf extract, white tea extract, epigallocatechin gallate
States of Nutritional Support For Dietary Supplement:	Helps curb the appetite; beneficial effects on health and well-being associated with the antioxidant activity of polyphenols naturally found in green tea

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,


David Edell, CEO
CCA Industries, Inc.